| Notice of Allowability | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/020,882 | TOBE, SHELDON | |
| | Examiner | Art Unit | |
| | JOHN PAK | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Applicant's response of 5/22/2007*.

2. ☒ The allowed claim(s) is/are *24, 26, 31-37 [renumbered as 1-9]*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   **Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20070804* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600

This Office action is in response to applicant's amendments and remarks of 5/22/2007 and telephone interviews of 7/31/2007, 8/2/2007 and 8/3/2007 (see attached Interview Summary).

**Rejoinder**

Claim 24 (as presently amended hereinbelow) is directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims directed to kits, method of preparing and method of treating patients with the same product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 3/19/2004 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Neil Hughes on 8/3/2007.

**Amendments to the Claims**

**CANCEL** claims 1-23, 25 and 27-30.

Claim 24. (Currently amended) A sterile calcium free low bicarbonate dialysis concentrate composition containing sodium chloride, magnesium chloride and sodium bicarbonate for continuous renal replacement therapy and for use in the preparation of a sterile calcium free dialysis solution comprising sodium chloride (NaCl), magnesium chloride ($MgCl_2$), and a concentration of sodium bicarbonate ($NaHCO_3$) sufficiently low so as to allow preparation of the sterile calcium free dialysis solution for continuous renal replacement therapy, having ion concentrations of Na 140 ± 14 mmol/l, Mg 0.75 ± 0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and $HCO_3$ 25.0 ± 2.5 mmol/l.

Claim 26. (Currently amended) A sterile calcium free low bicarbonate dialysis concentrate composition containing sodium chloride, magnesium chloride and sodium bicarbonate for continuous renal replacement therapy and for use in the preparation of a sterile calcium free dialysis solution comprising sodium chloride (NaCl), magnesium

chloride ($MgCl_2$), and a concentration of sodium bicarbonate ($NaHCO_3$) sufficiently low so as to allow preparation of the sterile calcium free dialysis solution for continuous renal replacement therapy, having ion concentrations of Na 140 ± 14 mmol/l, Mg 0.75 ± 0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and $HCO_3$ of from 20 to less than 30 mmol/l.

Claim 31. (New) A kit for preparing a sterile calcium free dialysis solution comprising the sterile calcium free dialysis concentrate composition of claim 24 or 26 and optionally instructions for use.

Claim 32. (New) The kit of claim 31, further comprising sterile water sufficient to dilute the concentrate to a sterile calcium free dialysis solution comprising Na 140 ± 14 mmol/l, Mg 0.75 ± 0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and $HCO_3$ 25.0 ± 2.5 mmol/l.

Claim 33. (New) A method of preparing a sterile calcium free dialysis solution comprising diluting a sterile calcium free dialysis concentrate composition of claim 24 or 26 in a sufficient amount of sterile water to prepare a sterile calcium free dialysis solution comprising Na 140 ± 14 mmol/l, Mg 0.75 ± 0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and $HCO_3$ 25.0 ± 2.5 mmol/l.

Claim 34. (New) A method for providing continuous renal replacement therapy to a patient comprising administering a sterile calcium free dialysis solution prepared according to the method of claim 33 in conjunction with a regional citrate anti-coagulant solution to a patient in need thereof.

Claim 35. (New) A method of preparing a sterile calcium free dialysis solution or infusate comprising diluting a sterile calcium free dialysis concentrate composition of claim 24 or 26 in a sufficient amount of sterile water to prepare a sterile calcium free dialysis solution or infusate comprising Na 140 ± 14 mmol/l, Mg 0.75 ± 0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and $HCO_3$ 25.0 ± 2.5 mmol/l.

Claim 36. (New) A method for treating acute renal failure in a critically ill patient without introducing calcium into the blood removed from the patient during dialysis comprising administering a sterile calcium free dialysis solution prepared according to the method of claim 35 in conjunction with a regional citrate anti-coagulant solution to a patient in need thereof.

Claim 37. (New) A method for providing hemofiltration to a patient comprising administering a sterile calcium free infusate prepared according to the method of claim 35 in conjunction with a regional citrate anti-coagulant solution to a patient in need thereof.

**Amendment to the Specification**

Specification page 1, line 3 (immediately below the Title): insert the following application data - - - This application claims benefit of Provisional Application 60/256,493, filed on December 20, 2000. - - - .

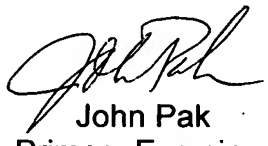
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Pak
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